Citation:

Maskarinec G, Aylward AG, Erber E, Takata Y, Kolonel LN. Soy intake is related to a lower body mass index in adult women. *Eur J Nutr.* 2008 Apr; 47(3): 138-144. Epub 2008 Apr 22.

PubMed ID: 18427855

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the effect of soy intake with body weight over the lifespan of women of Caucasian, Japanese and Native Hawaiian ancestry.

Inclusion Criteria:

Participants from two previous studies:

- The Breast Estrogen and Nutrition study (BEAN) and a nested case-control (NCC) study of mammographic densities, which was a subset of the Multiethnic Cohort (MEC)
- NCC subjects were primarily post-menopausal women.

Exclusion Criteria:

- 74 women who did not return the Life-time soy questionnaire (LTSQ)
- The BEAN study excluded women taking hormones and those who reported taking more than six soy servings per week.

Description of Study Protocol:

Recruitment

- 1,193 women from the NCC
- 225 women from the BEAN project.

Design

- All women completed a diet and self-administered Diet and Health Questionnaire (DHQ) at entry into the study
    - Weight and height at 21 years and current weight and height were self-reported by the

participants
    - Ethnicity was also self-reported
- A subset of 356 women completed the same questionnaire again at five years
- To estimate soy exposure from birth, a one-page questionnaire was used to correlate the usual serving sizes of soy foods by stage of life.

Dietary Intake/Dietary Assessment Methodology

- Estimated by self-reported intake using DHQ
- Soy intake estimated using the Life-time Soy Questionnaire (LTSQ), a self-reported questionnaire asking for annual frequency of usual serving sizes of four categories of soy foods during infancy, childhood, adolescence, early adulthood and late adulthood.

Statistical Analysis

- Characteristics of the study populations were stratified by ethnicity
- Results for continuous variables reported as means and standard deviations (SD)
- Results for categorical variables reported as chi-square
- Pair-wise comparisons between ethnic groups for variables of interest were examined using Tukey's Studentized Range test
- To examine the reliability of the questionnaire recall PROC FREQ in SAS was used to calculate the weighted κ values by stage of life for the 356 women who completed the LTSQ twice
- Analysis of variance was applied to determine the relationship of soy intake to BMI and to estimate least square means by soy intake category
- To test for trends, a linear variable of zero (no servings), one (less than one serving per week), two (more than one serving per week), and three (more than two servings per week) was applied
- All models were adjusted for confounding variables:
    - Ethnicity
    - Age
    - Education
    - Percent calories from fat
    - Energy intake
    - Physical activity
    - Age at menarche
    - Number of children
    - Age at first live birth.

Data Collection Summary:

Timing of Measurements

- Entry into one of two previous studies
- Subset of 356 women completed questionnaires five years after entry into study.

Dependent Variables

- *Variable 1:* Self-reported current height and weight was used to calculate BMI
- *Variable 2:* Self-reported height and weight (BMI) at 21 years of age.

Independent Variables

- Soy intake self reported on life time soy questionnaire (LTSQ)
- Annual frequency of consumption divided into four groups: None, less than one serving a week, more than one serving a week, more than two servings a week.

Control Variables

- Age
- Education
- Percent calories from fat
- Energy intake
- Physical activity
- Age at menarche
- Number of children
- Age at first live birth.

Description of Actual Data Sample:

- *Initial N:* 1,492 females
- *Attrition:* 1,418 females
- *Age and ethnicity:* Self reported:
  - Native Hawaiian: N=254, mean age 53.9±8.9 years
  - Japanese: N=606, mean age 57.9±9.4 years
  - Caucasian: N=456, mean age 55.0±10.4 years
  - Other: N=102, mean age 49.9±9.3 years
- *Anthropometrics:* BMI at study entry and at age 21 were significantly higher for Native Hawaiians, intermediate levels for Caucasians, with lowest BMIs for Japanese
- *Location:* Hawaii, United States.

Summary of Results:

- There were significant differences in characteristics between all ethnic groups studied
- BMI at study entry and 21 years were significantly higher for Native Hawaiians
- Caucasian women had the highest physical activity level, energy intake and alcohol level
- There was a significant trend for the association of adult soy intake with BMI at entry (P=0.02):
  - Women reporting more than two soy servings per week had a 0.7kg/m^2 lower BMI than women consuming no soy
  - When analyzed separately by ethnicity, the trend was only significant for Caucasians with 2.1kg/m^2 lower BMI (P=0.01)
  - The trend was stronger for post-menopausal women (1.2kg/m^2; P=0.01)
- The overall model with combined adult and child intake was significant (P<0.0001) with a difference of 0.9kg/m^2 between high and low soy intakes
  - After stratification by ethnicity the effect was only significant for Caucasians (P=0.001) with a 2.35kg/m^2
  - When weight change since 21 years of age was examined in relation to soy intake, the difference between high and low adult intake was significant (P=0.02); women in the low soy group had a weight gain of 0.05kg per year greater. This contrast was only significant for Caucasian women
- When a model examined the association of energy, vegetable, fruit, meat, fat and

carbohydrate intake as well as physical activity with adult soy intake while adjusting for covariates, only vegetable intake remained significant (P<0.001). Higher vegetable intake was associated with higher soy intake.

Author Conclusion:

The authors conclude that women consuming more soy foods during adulthood, especially Caucasian and post-menopausal women, may have a lower BMI. However, they point out that this may due to other nutrition factors and behaviors common in women with high soy intake.

Reviewer Comments:

- *Subject selection created dissimilar groups in that the inclusion and exclusion criteria from the studies from which this sample was taken from were quite different*
- *The method of reporting soy intake over life stages relies on retrospective self-reporting.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes

2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	No
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	Yes
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	???
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	???
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???

7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes